DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-06

December 11, 2001

Luciano Bonaldo, President
Netuno Trading Group, Inc.
7341 N.W. 79th Terrace
Medley, Florida 33166

Dear Mr. Bonaldo:

We inspected your seafood importing and warehouse facility, located at the above address, on June 26, 2001 and found that you continue to have serious deviations from the Seafood HACCP Regulations (21 CFR Part 123). These deviations, some of which were previously brought to your firm's attention, cause your fresh refrigerated scombrotoxin forming fish products such as mahi-mahi and mackerel to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

Domestic

You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for histamine producing fish lists monitoring frequencies at the storage critical control point that are not adequate to control the food safety hazard of scombrotoxin (histamine) formation. For example, the frequencies listed in your plan to monitor cooler temperature and adequate ice are "Every Lot" in lieu of every 4 hours as specified in your critical limits for storage.

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations for adequate ice at the storage critical control point listed in your HACCP plan for histamine producing fish to control the food safety hazard of scombrotoxin (histamine) formation. For example, your cooler temperature/ice monitoring record is not designed to document the ice checks during storage.

Imports

You must have written product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, the written product specifications listed in your standard operating procedure (SOP) are inadequate for imported scombrotoxin (histamine) forming fish species. Written product specifications for imported seafood products should be designed to ensure that the imported products are safe, free of adulteration, and are processed under sanitary conditions. The written specifications in your SOP address receiving practices by your firm but fail to specify the product specifications for histamine forming species to be followed by your foreign suppliers. This deviation was previously brought to your firm's attention in our letter of May 23, 2000.

You must implement an affirmative step, which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm imports various fish and fishery products from three foreign suppliers in Brazil and copies of their HACCP plans and letters of guarantee are not maintained on file at your firm. This deviation was previously brought to your firm's attention in our letter of May 23, 2000.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice (GMP) Regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your revised monitoring records, written specifications for imported products, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District